Template for a Registry Regulation

**When should this template be used?**

This registry regulation template should help anyone developing a registry that stores and manages health-related information of individuals or populations (data subjects). The template respects legal and ethical requirements and helps to set the framework in which the registry navigates including its purpose(s) and governance, its operational, data access, data transfer, and quality management procedures, as well as administrative details. The template can be used for all types of registries, whether a registry is developed for quality control/surveillance purposes or research purposes.

Even if originally set up for quality control or surveillance purposes, data collection and storage purpose have to be carefully evaluated in terms of data disclosure and associated data subject rights. As the amount of collected data increases, the likelihood to address research questions in a robust manner increases and research is eventually performed. Consequently, it is highly recommended to seek the advice of a designated Data Protection Officer or Institutional Review Board (e.g. institutional governance board) and/or submit your registry to the Ethics Committee (EC) when setting up a new registry or joining an existing registry (multi-centric national or international), even if research with registry data has not clearly been conceptualized, yet. For more details, please refer to the guiding principles for registries in human research issued by swissethics [1].

A registry can be mandated by the authorities or by law (i.e. highly specialized medicine registry). Whether mandatory or not, whenever a registry’s data is used to answer a research question that falls within the scope of the Human Research Act (HRA, Art. 2) [2], thus it must be evaluated by an EC.

**Authors of this template**

This registry regulation template has been developed by Médecine Universitaire Suisse (unimedsuisse), mandated by swissethics, Swiss Personalized Health Network (SPHN) and in collaboration with representatives from the following institutions: Centre Hospitalier Universitaire Vaudois (CHUV), Clinical Trials Center Zurich (Universitätsspital Zürich, USZ), Clinical Trial Unit St.Gallen (Kantonsspital St.Gallen, KSSG), Departement Klinische Forschung (DKF, Universitätsspital Basel (USB)), Hôpitaux Universitaires de Genève (HUG), l’Association des Hôpitaux de Suisse (H+), Médecine Universitaire Suisse (unimedsuisse), Swiss Group for Clinical Cancer Research (SAKK), Swiss Biobanking Platform (SBP) and Swiss Clinical Trial Organisation (SCTO).

**Support for this template**

The SPHN DCC offers guidance and support for the registry regulation template. Contact: info@sphn.ch.

**Change history**

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# Registry Regulation of [name]

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1. General provisions
	1. Scope

This regulation defines the purpose, the operational processes, and the organization of the registry [name of the registry]. It describes the requirements for collecting, storing, processing, managing and sharing health–related registry data.

* 1. Applicable laws, recommendations, and institutional directives

This regulation relies on the applicable Swiss and cantonal legal frameworks, in particular:

* the Federal Act on Data Protection (FADP), the Cantonal law(s) on Data Protection [2],
* the Federal Human Research Act (HRA) and its ordinance [3],
* the Cancer Registry Act (CRA) [4].

The registry is compliant with the following guidelines:

* guiding principles for registries in human research issued by swissethics and the recommendations for the setup and operation of health registries, developed by ANQ, FMH, H+, SAMS and unimedsuisse [1].

Note: Some registries, such as a mandatory registry, may rely on further laws and guidelines. If so, please indicate the laws and guidelines that must be complied with. Some suggestions can be found in the following paragraph.

This registry has been specifically setup according to the mandate by (specify institution / authorities/ association).

If applicable: Indicate institutional directives that must be followed*.*

Registry compliance with regulatory requirements has been assessed by […], and has been granted the following review number [BASEC-ID/ IRB Identification number].

* 1. Abbreviations

Please adapt abbreviation list as needed.

**ANQ** – Association nationale pour le développement de la qualité dans les hôpitaux et les cliniques

**ATC** – Anatomical Therapeutic Chemical Classification System CRF – Case Report Form

**CHOP** – Swiss Classification of Surgical Operations (Classification Suisse des Opérations Chirurgicales

**CTU** – Clinical Trial Unit

**DICOM** – Digital Imaging and Communications in Medicine EC – Ethics Committee

**FADP** – Federal Act on Data Protection

F**MH** – Foederation Medicorum Helveticorum

**FOPH** – Federal Office of Public Health

**HRA** – Human Research Act

**H+** – Association des Hôpitaux de Suisse

**ICD-O3** – International Classification of Diseases for Oncology, 3rd Edition **ICD-10-GM** - International Classification of Diseases, 10th Revision, German Modification IRB – Institutional Review Board

**LOINC** – Logical Observation Identifiers Names and Codes PROMS – Patient Reported Outcome Measures

**SAMS** – Swiss Academy of Medical Sciences

**SNOMED CT**- Systematized Nomenclature of Medicine Clinical Terms SPHN - Swiss Personalized Health Network

**TPA** – Therapeutic Products Act

**UCUM** - Unified Code for Units of Measure

**SPHN** DCC - Swiss Personalized Health Network Data Coordination Center

1. Description of the registry
	1. Purpose and scope of the registry

This registry has been established to [investigate a disease/collect data in the context of xxx (i.e. public health, post-marketing surveillance, other surveillance (i.e. infectious disease outbreak, treatment/intervention/therapeutic evaluation, quality improvement, benchmarking, evaluation of changes in clinical practice, cost evaluation, etc.) /exchange data with xxx/establish a framework for/establish digital biomarkers/ collect structured qualitative data for registry-based research projects].

Describe the general aim of the registry, (see above some suggestions) explain why the registry is needed and potential insights it may yield.

* 1. Data
		1. Data subject population (cohort definition)

The data are collected from the following population [outpatients, inpatients, healthy citizens, vulnerable persons (children, elderly persons, persons with disabilities etc.].

Describe in detail the data subject population (diagnosis/age/gender/ exclusion/inclusion criteria /etc.).

Specify data origin and type of collection (multiple types may apply), for example, whether data are collected

* from standard healthcare (routine data),
* directly collected for the purpose(s) of the registry (primary use), and/or
* used from other existing sources like medical registries, clinical trials and/or research projects etc. (secondary use).
* In the following coded
	+ 1. Data collection events

This registry is [monocentric/multi-centric], collects data [within Switzerland only/in the following countries (provide list of countries)] under the lead of [responsible representative (institution/authorized representative of consortium].

Monocentric means the data is collected only from one site/ data providing institution.

Multicentric means the data is collected from several sites/ data providing institutions.

A detailed list of the data domains of the intended registry data, including data models and standards are given in Appendix I (Table I.1).

Provide details on data domains, data models, and standards in Appendix I (Table I.1).

The procedure for data collection is [a continuous manual data collection/an automated regular processed data collection /a bulk transfer of data at a specific time point]. It will adhere to the following data collection timelines: [Insert details].

Further details on the data collection are given in Appendix I (Table I.2).

* + 1. Data scope and specification

A detailed list of collected registry data, including variables, concepts, data models, standards, formats, value sets and units is described in Appendix I (Table I.3).

Provide a detailed list of variables in Appendix I (Table I.3)

* + 1. Data interoperability

The registry will ensure data interoperability as defined by the FAIR principles [8] (I1, I2 and I3), in the following way:

Principle I1: Language for knowledge representation

The registry data can be exchanged by a common language for knowledge representation, which is both human readable and machine understandable. Describe the data exchange format (e.g. RDF, OWL, or JSON-LD)

The model of the data is following an international or national data schema. Describe the data schema used (e.g. CDISC, SPHN or OMOP). This can be either done globally (Table I.1 in Appendix I) or for each concept/variable Table I.3 in Appendix I). The schema / data model and / or data dictionary are openly available [insert link or table of links].

Principle [I2: Vocabularies that follow FAIR principles](https://www.go-fair.org/fair-principles/i2-metadata-use-vocabularies-follow-fair-principles/)

The registry uses the following standards as controlled vocabulary for description of its variables:

* INSERT LIST:
* Standard 1
* Standard 2
* ...

as well as for data and value sets:

* INSERT LIST:
* Standard 1
* Standard 2
* revo...

Further details are covered in Appendix 1 (Table I.3). The standards chosen follow the recommendation of

[insert reference here e.g. SPHN [6]].

* + 1. Sensitivity of data and de-identification

The data collected contains sensitive personal information and is stored in a coded or anonymized form. Data are de-identified following dedicated de-identification rules ensuring appropriate minimization of the re-identification risk. Specific technical and organizational measures are taken for the transmission, storage, and processing of this data to ensure data privacy and safety (see chapter 4.1).

Describe the rules chosen to de-identify data resulting in coded or anonymized data. Note that in the Human Research Act (HRA), the term "coded data" is used for pseudonymized data. Given that the German term for "coded data" (i.e., "verschlüsselte Daten") used in the HRA is misleading as it may be misinterpreted to refer to "encrypted data", the term "pseudonymized data" might be rather uniformly used instead of "coded data". Please adapt according to your preferences. SPHN provides de-identification guidelines following a risk-based approach to evaluate the project specific risk of re-identification. The guidelines include a template to create a project specific risk profile including de-identification rules, that can be selected according to the project specification [7].

Principle [I3: Qualified references to other (meta)data](https://www.go-fair.org/fair-principles/i3-metadata-include-qualified-references-metadata/)

If applicable: The registry is connected to the following registries/biobanks: provide complete list of connected registries and/or biobanks and specify the nature of connection (i.e. receiving/ providing data).

If applicable: This data will be combined with [health insurance data/statistical office data/other registries outcomes from genetic analysis/outcomes from analysis of bacteria from patient environment/ etc.].

If applicable: The data from the following pre-existing data collections were incorporated in the registry [name of registry/BASEC-ID/etc.].

* 1. Consent of data subjects

Note: The need for a data subject’s consent depends on the defined purpose and scope of the registry and must meet the guiding principles for registries in human research issued by swissethics [1].

The written and signed informed consent of the data subjects (or the documented right to dissent (HRO, Art. 32)) is required whenever a registry is planned or used for health research purpose(s).

* The General Consent can be used in case of further use of routinely collected health-related personal data.
* A specific consent must be used when additional, non-routine health-related personal data is collected (e.g., through a questionnaire which is not standard of care).
* The Opt-out option can be used for a registry collecting coded non-genetic data only. Nevertheless, the data subjects need to be informed (HRO, Art. 32) and the information needs to be documented. If so, describe and document how data subjects are informed about their “right to dissent”. Be aware that the “right to dissent” can be difficult to document.

Note: Opt out option means that if the data subject has not declined the General Consent, non- genetic data may be used.

* For any other situation, a consent must allow the further use of personal data.

A consent is not required for quality control registries, registries required by authorities or set up as part of health policies, special registries that underlie a specific legislation (i.e. opt out process for cancer registry, etc.), or when data are collected and used anonymously. If your registry applies to one of the above situations, briefly explain why an informed consent is not required.

Please choose one of the following options:

Option 1: This registry does not need consent because [provide here the reason why; e.g. waiver from ethics commission because the registry is established for quality controls purposes and subsequent usage of registry data is only for quality projects

Or

Option 2: The collection, storage, and use of data for research purposes is based on a [specific consent allowing further use of data/the General Consent]. Consent will be freely given and preceded by the appropriate information. The consent status given by the data subject will be documented and the signed consent form will be stored locally for the duration of the registry/ and archived xy years after the termination of the last research project resulting thereof.

Consent can be revoked at any time and without justification by the data subject. Such a revocation does not entail any prejudice especially regarding the medical care of the data subject. Revocation modalities are described in the consent form.

In the case of minors or adults incapable of judgment, written consent is obtained from the minor and/or legal representative or from the sole legal representative, respectively. The status of a legal minor or adult incapable of judgment is documented to facilitate the recollection of the consent when acquiring or recovering capacity to consent. Include a dedicated description of consent collection for those cases, if needed.

Or

Option 3: The competent EC authorizes the collection and use of data for research purposes under the conditions provided in [article 34 of the HRA](https://www.fedlex.admin.ch/eli/cc/2013/617/en#art_34) (provide BASEC-ID).

The technical measures to identify and remove data of specific patients are as follows: [Please specify details.]

Process that ensures documentation of consent withdrawal and re-use option of concerned data: [Please specify details.]

If applicable: Specify process and technical measures to remove patient data after consent revocation.

* 1. Data subject’s rights to information
		1. Duty to provide information

The data subject should receive relevant information related to the registry and the collected data according to the applicable data protection laws. In cases where it is not possible to provide the information or where providing the information requires disproportionate effort (registries without consent, cases under Art. 34 HRA), the relevant information is to be provided upon request of the data subject.

Delete this part if non-personal data is used for the Registry.

* + 1. Right to consult

The data subject has the right to enquire whether their personal data are being processed. The data subject can consult all personal related information stored in the registry to amend, correct or delete as necessary, in so far as they are not complete or correct. The right to request deletion can be subject to mandatory legal requirements for the registry concerned. The data subject is allowed to ask to be informed of what has been done with the data. The data subject can contact the local registry responsible person as per the provisions of Section 7 « Communication » or it is indicated in the consent document.

Delete this part if non-personal data are used for the Registry.

* + 1. Return of results (if applicable)

The data subject has the right to be informed about incidental findings pertaining to their health in accordance with the collected consent and the applicable legislation and ethical standards. If returned, these results should meet at least the following criteria: analytical validity, clinical significance, and be actionable. The return of results will follow this process:

 Insert a process description including the responsible persons/boards/governance bodies.

Delete this part if non-personal data are used for the Registry.

2.4.4 Registry of activities

The registry communicates relevant information concerning its organisation, operational processes, and activities via [its website/annual activity report/newsletter/scientific publications/conference presentations/ etc.].

* 1. Funding of registry

The registry is funded by [public/private/public and private] funds from [indicate source(s) of funding] for a duration of [indicate funding duration].

The long-term funding is ensured by [indicate source of funding].

Or

The long-term funding is not yet secured. This regulation will be amended as soon as a long-term funding source is identified.

* 1. Conflict of interests

Indicate any potential conflicts of interests, specify who in the registry organisation has these conflicts of interests and why (i.e., with donors, sponsors, other groups of interests, etc.). Additionally, describe how you plan to manage each identified conflict of interests.

* 1. Registry duration and termination

The registry will operate [until date/for an indefinite duration/for a maximum number of x data subjects].

The registry data will be [anonymised and made available on an open access platform and archived for xx years and subsequently destroyed (Destruction policies should be attached /passed to another registry] after termination of this registry.

If applicable: The duration of the registry could be prolonged if [financing is guaranteed/the demand widely exists/the Registry decides about an extended duration during an annual meeting/the commissioning institution (i.e. Federal Office of Public Health (FOPH)) requires its prolongation/the research question of the registry has not been answered yet/etc.]. If the duration of the registry is prolonged, this document, and particularly this section, needs to be amended three months prior termination.

1. Governance
	1. Establishment of the registry

The registry [name of registry] was founded on the [date of registry creation] and the data collection started/ will start on [date of first data collected].

* 1. Legal status

The registry is established as a [foundation – name, association – name, company – name, governmental organization – name].

Or

The registry is an autonomous entity established under the Cantonal law of [canton]or under other

Or

The registry is linked to the [Department/Service/Unit] of [name of the Institution] and has no independent legal personality.

* 1. Structure

The registry is organized and structured as following:

Please provide an organizational chart/organigram of your registry and list each unit/committee (i.e. strategic direction, operational direction, administrative direction, registry management committee, scientific committee/data access committee, etc.) (i.e. scientific committee – ensures continuous scientific relevance of registry, evaluates registry-based research projects willing to access data from this registry, etc.) and briefly describe their roles and functions, including full names, addresses of key individuals. Address the role of the patients.

1. Operational procedures
	1. Data processing
		1. Security

The Registry ensures appropriate confidentiality, integrity, availability, and resilience of the systems with regard to the processing of collected data. Appropriate technical and organizational measures are implemented and maintained to protect the personal data against accidental or unlawful destruction, loss, alteration, or unauthorised disclosure or access. The efficacy of these measures is regularly reviewed and assessed, and corrective measures shall be immediately implemented in case of suspected data security breach.

A documentation of the technical and security measures is documented and/or available by contacting [e.g. the main representative of the Registry] (see Section 7).

Provide a list of technical and security measures that apply to the registry or provide a reference/responsible person that provides the documentation of implemented security measures. In terms of instructions and training, make sure certificates or documentation is available/documented. For example:

The technical and organizational measures ensure that it is possible to examine and verify if, when and by whom data was processed.

The Registry provides adequate organizational measures ensuring that any person authorised to access the data:

* is diligently and appropriately selected, instructed, and supervised, in particular through the availability of adequate confidentiality and data protection procedures, regular data protection and privacy trainings, documentation of all organisational measures.
* List of authorized persons, with start and end dates, with certificates of training, xxxx is available and updated xxx by xxx.
* respects and maintains the confidentiality and security of the data.
	+ 1. Personal data

Personal data are processed in compliance with applicable data protection laws. Any personal data of data subjects will be obtained, handled, or used in accordance with all relevant laws and regulations. Any informed data subject consent required for performing research will be obtained prior to the use of the data subject’s data.

* + 1. Storage and transfer

The data is only stored for the purpose of the registry.

The registry database is built and managed with [name of the system/web application].

The web server is managed by [… and located in …]

The database server is managed by [… and located in …]

[In case there are two different servers, communication between both and with the end-user occurs via […].]

Data are [automatically imported via data warehouse/manually imported/other] into [name of the system/web application]. […% of the data are automatically sent to the registry].

Data is transferred using a [secure web connection, etc.]

The registry performs regular checks to ensure that the duration of the storage of data complies with the current and applicable data protection regulations.

Provide adequate information about data storage and transfer including a timeframe concerning regular checks.

* + 1. Backup system and recovery plan

The registry ensures that all processing activities conducted by registry personnel adhere to the institutional Data Protection Policy. A backup routine and recovery plan are in place to protect data against misuse, loss, and damage. Consider the institution that is sending data to registry and also if it is not the same institution hosting the registry.

A backup is performed automatically and on a regular basis. Describe the backup schedule. The frequency of the backups depends on the frequency of data entry modifications.

In case of user error, failure of equipment, catastrophic event, or deliberate intrusion or hacking, the personnel is aware of the immediate actions to take. Describe the actions to take (i.e. contact details with IT service, disconnect affected workstations, communicate with personnel, change password, etc)..

Emergency contacts (phone, mail):

* 1. Linkage to the source registry(ies)

Linkage of the registry to [name of the administrative/official data registry, …] is guaranteed. Describe the process and how it is done.

1. Granting access to registry data
	1. Terms of access

The registry ensures appropriate protection against unauthorised or unlawful data access or processing in any form (e.g., reading, copying, altering) and against accidental loss, destruction or damage, using appropriate technical or organisational measures as described in section 4.

The registry will only grant access to data if the requirements described in Appendix II (section A) are met and upon authorisation of the requestor by the respective committee [data access committee, steering board of registry, other authorized bodies] following the governance structure of subsection 3.3.

* + 1. Data access to the registry by registry’s collaborators

Indicate who has access to registry data and in which form (identified, coded or anonymized) [head of registry, data manager, quality controller, other]. If data are coded or anonymized describe how the de-identification process is done (if not mentioned in Section 2) and how re-identification, in case it is needed, is handled. Describe or inform about the different access levels/roles (i.e. administrator, etc.). Be aware that solely data provider staff can have access to identified data in a multicentre registry setting unless there is specific agreement in place allowing the access to identifying data by external persons.

Please add a data flow describing who of the participating parties has access to data and who is providing the data. Also who is responsible for de-identifying the data.

Solely the registry collaborators listed in Appendix II (section B) have the right to change, delete or export data.

List key persons/roles that have these rights and indicate them in Appendix II (section B). If there is a dedicated audit trail applicable add the process accordingly.

* + 1. Data access to the registry by third parties

Third parties are granted access if the requirements described in Appendix II are met and after the terms and conditions of data disclosure have been regulated in a legal agreement (i.e. Data Transfer and Use Agreement). Data access is [time limited/read-only/no export etc] and granted to a specified secured data location in line with 4.1.1 Indicate who has access to coded or anonymized data subject data in the registry database [registry manager, data manager, quality controller, researcher, other]. To access the data space, technical security measures must be in place, e.g. access log, 2F authentication.

* 1. Transfer of registry data

The registry ensures that any transfer of data is regulated and documented in a verifiable manner.

Please describe modalities of this documentation (e.g. keep a copy of the delivered data for x years or keep logs or specifications of the data for x years).

A legal agreement (i.e., Data Transfer and Use Agreement; Appendix IV) that regulates terms and conditions of data disclosure to third parties, data sharing and authorship on publications is available.

The obligations which have not been expressly attributed to the receiving party by the DTUA, remain under the responsibility of the registry.

If data is transmitted to a third party in another country, such cross-border transfers must be referenced in the prior consent, where consent is required. Equivalent security measures as the ones applicable in Switzerland must be implemented by the third party to ensure data subject privacy and rights.

If applicable: Swissmedic can be provided access to specific vigilance and market surveillance information systems that can be set up as registries (TPA, Art. 81a).

1. Quality assurance of registry

To ensure the reliability and robustness of the data, the quality of the registry is maintained throughout its existence and subject to periodic quality control measures. The measures comprise both the content of the registry (data quality as e.g. completeness, consistency, validity) and the legal aspects of the registry (embedding).

* 1. Registry maintenance

In intervals of [xy months/years (specify periodicity)], the registry is checked by [specify responsible person/body of registry/committee] to see whether the governance structure, measures for data security, and confidentiality still meet ethical and legal requirements.

To ensure sufficient data protection and confidentiality, it has to be predefined how data are recorded, extracted and provided for analysis purposes.

[Describe here e.g. that only de-identified data are recorded in the data registry, that e.g. upon data request from the registry, only a predefined data set is provided whereby the data are assigned to a new code, how those data are provided, and which prerequisites have to be met].

 [Describe briefly the planned controls, e.g

* Random controls of the informed consent
* Consent withdrawal process…
* Check if the roles and rights to access/process data are still valid
* ….]
	1. Data Quality

To ensure data quality, [describe any measures to mitigate erroneous data values as e.g. by implementing any rules in the database to detect and alert on values which are out of range, do not meet plausibility criteria, etc].

Furthermore, the registry ensures that every person involved in the management or maintenance of the data registry is trained for this purpose.

The quality of the data is [specify periodicity and extent] checked by [specify function] on a [defined set of criteria ensuring reliable data results of parameters on the most relevant objectives of the registry, either described here or in the separate quality management plan or monitoring plan] in order to identify whether:

* the data are complete (coverage and completeness) [describe how this is achieved, e.g. by monthly reports from the registry database and subsequent follow-up]
* the recorded data correspond to the data in the original sources (accuracy) [describe how this is achieved, e.g. by random source data verification]
* the recorded data are understandable, comprehensible, and plausible und coherent [describe how this is achieved, e.g. by remote data control in accordance with predefined criteria of predefined variables which are critical for data integrity and reliable results].
* the data extracted and transformed are still valid (also in terms consent status) and interoperable (as defined). Validity checks are performed after each data extraction and transformation.

The outcomes of the quality control are documented. The [specify responsible person/body of the registry/committee] reviews and evaluates the results and if necessary, initiates appropriate steps to eliminate quality deficiencies (CAPA).

1. Communication

For any questions or additional information, contact:

[*Name of contact person*]

[*Telephone*], [*generic E-mail address of registry*]

[*Address of the registry*]
[*Zip code*], [*City*]

General information about the registry is available on [*indicate relevant website*]. If applicable consent related information is available on [*indicate relevant website*].

1. Version history registry regulation

|  |  |  |  |
| --- | --- | --- | --- |
| Version | Effective date | Details of revision /change(s) | Responsible group/person for changes/amendment. |
| 1.0 |  | Initial release of registry |  |
|  |  |  |  |
|  |  |  |  |

1. References

1. swissethics Guidelines und Empfehlungen ANQ, FMH, H+, SAMS and unimedsuisse [swissethics.ch/en/themen/biobanken-und-datenregister](https://swissethics.ch/en/themen/biobanken-und-datenregister)

2. Swiss Federal Data Protection Act <https://www.fedlex.admin.ch/eli/cc/2022/491/en>

3. Swiss Federal Act on research involving Human Beings (Human Research Act)

 <https://www.fedlex.admin.ch/eli/cc/2013/617/en>

4. Bundesgesetz über die Registrierung von Krebserkrankungen , Krebsregistrierungsgesetz) <https://www.fedlex.admin.ch/eli/cc/2018/289/de>

5. [FAIR principles](https://www.go-fair.org/fair-principles/) (Wilkinson *et al.*, 2016: <https://doi.org/10.1038/sdata.2016.18>)

6. [SPHN Semantic Interoperability framework](https://sphn.ch/network/data-coordination-center/the-sphn-semantic-interoperability-framework/)

[7. SPHN Template Use case evaluation and risk assessment (De-identification guidelines)](https://sphn.ch/document/template-use-case-evaluation-and-risk-assessment/)

8. M. D. Wilkinson *et al.*, “Erratum: Addendum: The FAIR Guiding Principles for scientific data management and stewardship (Scientific data (2016) 3 (160018)),” *Scientific data*. 2019, doi: 10.1038/s41597-019-0009-6.

9. SPHN legal agreement templates <https://sphn.ch/services/dtua/>; <https://sphn.ch/document/dtua-without-processor-template/>

1. Signature(s)

Role and responsibilities

First, last name First, last name

Date, place: Date, place:

Signature: Signature:

Signature of institution/internal committee (duly authorized person of responsible institution or registry committee)

# Appendix I Description of data to be collected

**Table I.1: Data domains and corresponding standards**

Please list the top-level clinical data domains of the data of interest. They may include diagnosis, medication, laboratory tests, procedures, imaging data, multimedia data, units, oncology diagnoses or others. For each data domain, the corresponding data model(s) or schema(s) should be listed, e.g. SPHN, Observational Medical Outcomes Partnership (OMOP), Clinical Data Interchange Standards Consortium (CDISC), or others. Standards for the domains may include for example ICD-10-GM, SNOMED CT, ATC, LOINC, SNOMED CT, CHOP, DICOM, UCUM, ICD-O3 or others. Data model, schema, and standard should include the version intended to be used. SPHN offers advice and support to complete the tables accordingly. Please contact dcc@sib.swiss or info@sphn.ch.

|  |  |  |
| --- | --- | --- |
| **Clinical data domain** | **Data model / Schema (Version)** | **Data standard (Version)** |
| ... |  |  |
| ... |  |  |

Please append table as necessary.

Example:

|  |  |  |
| --- | --- | --- |
| **Clinical data domain** | **Data model / Schema (Version)** | **Data standard (Version)** |
| Diagnosis | SPHN:Billed Diagnosis (2024.2) | e.g., ICD-10-GM (2018) |
| Medication | OMOP:DRUG\_EXPOSURE (v5.4) | RxNorm (RxNorm\_05062024) |
| *...* |  |  |

**Table I.2: Source and mode of data collection**

List the source system(s) for the specific types of data. Detail the way the data is collected, how often or upon which trigger(s), Triggers may include particular events, e.g., deterioration of the condition, recurrence of a tumour, or change in concomitant therapy etc. Specify how data updates are intended to be carried out, e.g., when additional data becomes available or conditions of use change (e.g., consent revocation).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Data** | **Source** | **Mode of collection** | **Frequency or trigger of collection** | **Type of data update** (e.g., bulk or delta load) |
| ... |  |  |  |  |
| *...* |  |  |  |  |

Please append table as necessary.

Example:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Data** | **Source** | **Mode of collection** | **Frequency or trigger of collection** | **Type of data update** (e.g., bulk or delta load) |
| Demographics | KIS | Automatic via interface | once |  |
| Diagnosis | Discharge letter | NLP, manual (upon invoice preparation per administrative case (?)) | monthly |  |
| Laboratory results | LIMS | Automatic via interface | monthly, change in concomitant therapy |  |
| Consent | Patient health record information system | Automatic via interface | every three months | bulk |

**Table I.3: Variable list**

Please list all variables of interest and their corresponding attributes. List relevant data model, standard, and potential applicable restrictions, e.g., a specific subset of standardized codes or a specific unit or set of units in a standardized format (e.g., UCUM-format) like L, mol/mL, mm[Hg], a, or d.

Detail the intended format of the variable, e.g., the data type it shall be provided in or the desired precision (number of digits before and after the comma) for numerical values. A format itself may also be a type (see type column) in case of nested data concepts.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type** (Variable/ Concept or Attribute) | **Name** | **Data model** | **Standard** | **Value set / restriction / unit** | **Format** |
| **...** |  |  |  |  |  |
| **...** |  |  |  |  |  |

Please append table as necessary.

Example:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type** | **Name** | **Data Model** | **Standard** | **Value set / restriction / unit** | **Format** |
| **Variable/ Concep** | **AdministrativeSex** | **SPHN** |  |  |  |
| Attribute | Code |  | SNOMED CT | 248152002 | Female (finding) |; 248153007 | Male (finding); |32570681000036106 | Indeterminate sex (finding) | | URI |
| Attribute | Identifier |  |  |  | xsd:string |
| AttributesRecord datetime |  |  |  | xsd:datetime |  |
| **Variable/ Concept** | **Gene** | **SPHN** |  |  |  |
| Attributescode |  | HGNC; NCBI Gene; Ensembl or other |  | URI or SPHN:Code |  |
| AttributesOrganism |  |  |  | SPHN:Organism |  |
| AttributesTranscript |  |  |  | SPHN:Transcript |  |
| Variable/ Concept | Organism |  |  |  |  |
| AttributesCode |  | SNOMED CT; NCBI Taxon | for SNOMED CT: descendant of: 410607006 |Organism (organism)| | URI |  |
| **Variable/ Concept** | **Age** |  |  |  |  |
| Attribute | quantity |  | UCUM | min; h; d; wk; mo; a | sd:double,2 digit precision after the comma) |
| Attribute | determination datetime  |  | SNOMED CT; NCBI Taxon | for SNOMED CT: descendant of: 410607006 |Organism (organism)| | xsd:datetime |
| *...* | *...* |  |  |  | *.* |

# Appendix II Registry data request by third party and permissions

1. **Process for requesting registry databy third party**

Describe in detail the request process including the criteria to obtain data access.

Criteria for granting data access are for example:

* Aim and quality of the research project
* Requestor: Academia, industry, other
* Type of data: Coded/anonymized or aggregated data
* Rights and obligations of involved parties (use of data, data protection, publication rights, etc.) are documented

*Describe the decision procedure*

* Which body of the registry is involved in the decision (i.e. executive board of registry). You might want to refer to the governance section.
* Quorum, majority decision or unanimous decision

*Describe conditions for effective data delivery*

* Positive decision of the registry governance board (Steering board)
* Ethics Committee approval/statement if applicable
* Institutional governance board/data access committee approval if applicable, reference to governance section.
* Legal agreement in place (DTUA)
1. **Roles and Permissions**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Person** | **Contact** | **Role** | **Permission level** | **Start and End date** | **Permission details** |
| ... |  |  |  |  |  |
| ... |  |  |  |  |  |

Please append table as necessary.

Example:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Person** | **Contact** | **Role** | **Permission level** | **Permission details** |
| Beata Müsterli | beata.muesterli@registry\_x.ch | Administrator | Full permissions | receive, decrypt, read, change, delete or export data |
| Milica Checko | milica.checko@registry\_x.ch | Data managing | Data import and access | Receive, decrypt, and read data |
| Dat Amann | dat.amann@registry\_x.ch | Data validation | Data access | Read data |

# Appendix III Consent template

Add here the applicable consent form, e.g. the General consent form(s) or informed consent developed for the purpose of the registry. If no consent is necessary, delete this page.

# Appendix IV Data Transfer and Use Agreement

Add here the applicable Data Transfer and Use Agreement to regulate the data disclosure and regulations applicable to the data usage and transfer. SPHN provides Data Transfer and Use Agreements templates that can be used and adapted, if needed [9].